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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY SOCKET NO.
09/508,967	04/07/00	WAHLGREN	M 45300-59676

000466 HM12/0508
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EXAMINER

FIELDS, I

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/508,967

Applicant(s)

WAHLGREN ET AL.

Examiner

Ilesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 18-20, 25, 26 and 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-17, 21-24 and 27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 20) ☐ Other:

DETAILED ACTION

Applicant's election of Group III Claims 13-17, 21-24 in Paper No. 3 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

1. The drawings submitted with this application were declared informal by applicant. Accordingly they have not been reviewed by a draftsman at this time. When formal drawings are submitted, the draftsman will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch (703) 305-8404.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

2. Claims 22-23 are directed to non-statutory subject matter. The “use of a polypeptide” is a non-statutory subject matter, is the applicant attempting to claim the polypeptide (i.e. product) or a “method of use” of the polypeptide. Clarification is requested.

Claim Rejections - 35 USC § 112

3. Claim 13-17, 21-24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Claims are vague and indefinite in the recitation of a “functional analogue”. One of skill in the art would be unable to determine the metes and bounds of the limitations. For instance, what constitutes as a functional analogue? Without a clear definition as to what constitutes a “functional analog” one of skill in the art would be unable to replicate the claim.

Claim 14 is vague and indefinite in the recitation of “at least about”. One of skill in the art would be unable to determine the metes and bounds of the limitations. The courts have held that claims reciting “at least about” were invalid for indefiniteness

where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "at least about." (Amgen v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

Claims 13 and 15-17 are vague and indefinite in the recitation of "preferably". The phrase "preferably/such as" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 13-16 rejected under 35 U.S.C. 102(b) as being anticipated by Rowe et al.

The claims are drawn to the malaria erythrocyte membrane polypeptide set forth in SEQ ID NO:1 or a functional analogue thereof.

Rowe et al. (Nature 1997 Vol. 388 pp. 292-95) disclose a malaria erythrocyte membrane protein (PfEMP1). Rowe et al. further disclose that binding of infected erythrocytes to endothelial cells is mediated by PfEMP1 and is encoded by a specific *var* gene. Rowe et al. further disclose that PfEMP1 is a parasite ligand for resetting in *P. falciparum* and is therefore being viewed as a functional analogue of the polypeptide set forth in SEQ ID NO:1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe et al. in view of Su et al.

The claims are drawn to the malaria erythrocyte membrane polypeptide having a weight of about 100-300 kDa.

Rowe et al. does not teach of a malaria erythrocyte membrane polypeptide having a weight of about 100-300 kDa.

Su et al. (Cell 1995 Vol. 82 pp. 89-100) teach of *P. falciparum* genes (var) that encode 200-350 kDa proteins having properties of antigenic variant adhesion molecules.

Given that 1) Rowe et al. has taught that binding of infected erythrocytes to endothelial cells is mediated by PfEMP1 and is encoded by a var gene and that 2) Su

et al. has taught that *var* genes encode 200-350 kDa proteins in *P. falciparum* it would have been *prima facie* obvious of one of ordinary skill in the art at the time of the invention to combine the teachings of Rowe and Su et al. One would have been motivated to characterize proteins encoded by *var* in view of the teachings of Rowe et al. that that such proteins are potential parasite ligands.

6. Claims 13 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe et al. in view of Baruch et al.

The claims are drawn to a malarial medicament comprising a PfEMP1 fusion protein.

Rowe et al. does not teach of a malarial medicament comprising a PfEMP1 fusion protein.

Baruch et al (Proc. Natl Acad. Sci. 1996 Vol. 93 pp. 3497-3502) teach of a malarial medicament comprising a PfEMP1 fusion protein (See entire document)

Given that 1) Rowe et al. has taught of a malaria erythrocyte membrane protein and that 2) Baruch et al. has taught of a malarial medicament comprising a PfEMP1 fusion protein it would have been *prima facie* obvious of one of ordinary skill in the art at the time of the invention to make a malarial medicament comprising a PfEMP1 fusion protein. One would have been motivated to make a malarial medicament in view of the

teachings of Baruch et al. that the binding sites on PfEMP1 and cognate host cell receptors could be used in developing agents for the reversal of *P. falciparum* parasitized erythrocytes adherence and consequent occlusion of microvessels.

Status of Claims

6. No claims are allowed.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Iesha Fields

5/7/01



MARK NAVARRO
PRIMARY EXAMINER